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An Affiliate of Methodist Health System

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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm 1061  
Rockville, MD 20852

Friday, July 22, 2005

To Whom It May Concern:

We would like to formally submit comments to the draft guidance entitled: 'Guidance expiration dating of unit-dose repackaged drugs: compliance policy guide': Sec.480.200 (CPG7132b.11). First, we applaud the FDA for preparing this guide.

Under the discussion section point number 3. "The original container of drug product has not been opened previously and the entire contents are repackaged in one operation", we would like to know the rationale for this statement. In a hospital pharmacy practice, we repackage medications into unit of use form from bulk bottles. We use the expiration date established by the manufacturer once the original container has been opened as long as the product stays in the original container. We assume the dating on the manufacturer's original container is based on stability studies as long as the product remains in the original container.

We assign a new expiration date to the repackaged formulation based on United States Pharmacopeia chapters <661>, <671>, and <1146>. Under these chapters it does state the entire product from the original container must be repackaged.

Some products come in a form from the manufacturer that would lead to a great deal of waste if we follow the proposed standards in your guide. This would have a great financial impact to hospitals that repackage medications for their patients. Additionally, to be in compliance with the Joint Commission Medication Use Standard MM. 2.20 Element 10. "Medications in care areas are maintained in the most ready-to-administer forms available from the manufacturer or if feasible, in unit-doses that have been repackaged by the pharmacy or a licensed repackager," hospitals are asked to repackage if a product is not available in a specific dose for a patient.

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We would like the FDA to reconsider this statement based on the aforementioned standards of practice.

If you require any additional information please do not hesitate to contact me at my office. Thank you for your time and opportunity to comment on this docket.

Sincerely,

A handwritten signature in black ink, appearing to read "Fred Massoomi, Pharm.D.", with a stylized flourish at the end.

Firouzan 'Fred' Massoomi, Pharm.D.  
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